REMARKS

Claims 1-10 and 13-20 have been examined. No claims have been amended. Reconsideration of the claims in view of the following remarks is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 1-7, 10, 13-18 and 20 have been rejected under 35 U.S.C. § 103 as being obvious in view of Duncan and Walker. This rejection is respectfully traversed.

As now amended, independent claim 1 claims a method for treating an infected implant area of a knee joint. The method utilizes a tibial component having a tray, a central stem and a posterior stabilizing component. The central stem is inserted into the tibia (along with the antibiotic impregnated material). This provides stability to the tibial component while it is attached to the tibia. Further, the tibial component may be easily removed when ready to replace it with a permanent implant. Also, the antibiotic impregnated material is used to treat the infected area.

The method of claim 1 also uses a femoral component that is formed of an antibiotic impregnated material using a mold. The femoral component comprises a one-piece, integral design that includes two outer surfaces and a center section having a recess that is configured to interact with the tibial component. The femoral component is attached to the femur so as to completely cover the distal femur using an antibiotic impregnated material, thus treating any infection around the femur. Also, the antibiotic impregnated femoral component has more stability by encapsulating the entire distal femur. Furthermore, since the femoral component is attached to the femur using additional antibiotic impregnated material, it treats any infection around the femur.

When the tibial component and the femoral component are interfaced, the posterior stabilizing protrusion fits into the recess of the femoral component, with the two outer nails resting on the tray. This configuration provides anterior and posterior as well as lateral and medial stability to the knee joint.

In summary, the method of claim 1 produces a temporary knee joint that is highly stable at three interfaces while also being easily removable when the infection has subsided. These three interfaces are between the tibial component and the tibia, between the femoral component and the femur and between the femur component and the tibial component. Further, after the infection has been treated, the site may be accessed and these components easily removed.

It is respectfully submitted the combination of Duncan and Walker to teach these features is improper in that there is no teaching or suggestion to combine the arthritic treatment scheme of Walker with that of Duncan. Indeed, Walker actually teaches away from using antibiotic cements by permanently affixing joint replacements when treating arthritis. Moreover, the rejection is based on two patents for treatment of two separate clinical diseases of the human joint, thus rendering the combination improper. Specifically, Duncan describes a two stage treatment of infected total joint replacement while Walker describes an early and obsolete implant for knee arthritis treatment.

Duncan describes treatment of an entirely different clinical joint disease than Walker, making the combination of teachings improper. Neither the Duncan nor the Walker patents consider treatment of the other's target disease in description or intent. Each patented treatment described is for different diseases that have the presence or absence of a separate living organism in the human joint at the time of respective application which requires radically different treatment methods. The difference of each of these applications is designed for opposite and entirely different clinical diseases and have been mutually exclusive for nearly three decades.

More specifically, Duncan is relied up to teach a two-stage treatment for septic total joint replacement in order to avoid amputation as ultimate failure. Walker, on the other hand, describes single stage treatment of aseptic or uninfected joint in an arthritic knee to avoid the discomfort of arthritis. There is no provision in either reference for treatment of the other different target disease or condition. As such, there is no suggestion in the references, or generally known in the art, to combine teachings directed to two distinctively different diseases.

Attempted combination of the Examiner's cited treatments as suggested for either condition would result in failure and further surgery and does not meet an acceptable standard of care.

For example, Duncan's application provides joint motion but not joint or component stability. Dislocation and subluxation of an infected joint and cement components treated with this method eliminates motion and results in additional surgery. Hence, the method of claim 1 of the present invention includes structural components to avoid this complication. The structural components of claim 1 are particularly useful after radical tumor-like removal of infected joint tissue, including the numerous normal stabilizing ligaments of the normal knee. After such a procedure, all joints become inherently unstable and able to dislocate which requires additional surgery to correct. This radical tissue removal is required in the treatment of all infected joint replacements. Dislocation and subluxation is commonly encountered in the first-stage treatment using the Duncan method. Claim 1 of the invention is employed to deal with such issues.

Furthermore, Duncan does not provide placement of a tibial component that is comprised of an all polyethylene component (see claim 3). The tibial component described by Duncan does not have an elongated stem which provides implant stability at the bone/implant interface. Such features, as claimed in the present application, prevents bone loss from unstable component fixation seen in the Duncan method. Additionally Duncan does not provide stability at the femoral and tibial component interface. The current claims provide for the posterior tibial implant post on the all polyethylene component (claim 3) which gives all directional stability not addressed in the Duncan patent and is an advancement of treatment for the same clinical disease.

Stability in an articulating design without bone loss or cement debris is provided by the method of claim 1 and leads to joint rehabilitation during the after the first stage treatment of septic joint replacement. This provides a superior end result of joint motion and stability after second stage revision. Hence, the method of claim 1 is important in preventing joint dislocation and bone loss after treatment for infection of total joint replacement. This provides a solution for the clinical problem of instability and dislocation after the first stage treatment of septic total

knee replacement because it provides stability at the bone/tibial implant interface and the tibial/femoral/knee joint interface not described in Duncan's applications.

The Office Action appears to rely on Walker to teach such stability. However, Walker's design describes treatment of a different disease process (arthritis) and has been obsolete for more than two decades for its intended application of joint replacement for arthritis. Walker's patent was not designed for implantation in a septic joint. In fact, implantation as described in a septic joint will aggravate the disease predictably. Walker's method of application in an aseptic and arthritic joint is that of maximal cement interdigitation into bone to provide a long lasting bone/component interface without loosening. This is directly opposite to what is claimed in claim 1 which uses an antibiotic cement that allows the components to be easily removed (see claims 8 and 9). Hence, Walker directly teaches away from the claimed invention.

Walker's design was one of the original designs used to treat uninfected aseptic knee arthritis with early total knee replacement. It was historically found to have limited longevity secondary to loosening from aseptic bone and is not in use today. Moreover, Walker describes the use of a metal and polyethylene components that provide stability and longevity in treatment of aseptic uninfected total knee replacement that lasts for years. In contrast, the method of claim 1 uses an antibiotic bone cement that is intended to be only temporary. The Walker implant utilizes a metal alloy component which provides persistence and aggravation of any infection. This would result in a failure rate of nearly one hundred percent if Walker's method was applied to a septic joint. Hence, Walker teaches directly away from using it's components in a total knee replacement procedure. Published treatment success rates with the current method of claim 1 is ninety-four percent. This would not have been expected in view of the teachings of Walker and the knowledge available to one of skill in the art.

Applicant further notes the recitation in the office action that "It would have been obvious to one having ordinary skill in the art at the time of invention to combine methods of manufacturing and implanting taught by Duncan with the polyethylene tibial and femoral structures components taught by Walker to provide the implant with increased gripping retention and stability." Applicant disagrees. If the techniques of Duncan and Walker, each designed for

a different purpose, were combined as suggested it would result in treatment outside of the standard of care, result in a high rate of microbiologic failure. Since Walker's tibial structure was designed for an aseptic joint application for arthritis, implanting it in a preexisting and infected total joint replacement without the modifications present in this application would result in an unacceptable failure rate.

The method of claims 1, 8 and 9, are employed specifically provide desirable early loosening in the first stage of standard two-stage treatment of joint infection. This method of treatment of septic total joint is designed where early loosening of the joint components is actually desirable and allows easier removal of this component when the second stage operation is performed three months after the first stage application described. This provides minimal bone loss with component removal. Secondarily this component design provides knee stability during the treatment interval between the first and second stage surgical treatment. The opposite is taught by Walker which permanently affixes components to the bone.

In summary, Duncan describes a method which does not provide the stability required by claim 1. Further, Walker teaches away from using a removable bone cement to affix the components and to make the femoral component, particularly because Walker is intended to treat a completely different disease. As such, it is respectfully requested that the section 103 rejection of claims 1-7, 10, 13-18 and 20 in view of Duncan and Walker be withdrawn.

Claims 8, 9 and 19 have been rejected under 35 USC 103 as being unpatentable in view of Duncan, Walker and Shaffer. These claims are distinguishable over Duncan and Walker for at least the reasons previously described. Further, applicant disagrees that the Shaffner method is equivalent to the claims of the current application. The Shaffner device is an implant made from antibiotic cement over an "endoskeleton". However, clinically these rebar type of cement coated endoskeletons have proven to disintegrate in the patient and result in bone loss and cement debris since they actually articulate with the patient's boney socket rather than a smooth articular surface of an antibiotic cement coated acetabular implant. Consequently they have never made it "to market" because of these inherent problems. With the methods of claims 8, 9 and 19, the implant does not collapse as in Shaffner's design, nor result in bone loss or

cement debris generation as in Duncan's design. Hence, these claims are distinguishable for this additional reason.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

Date: April 23, 2007

/darin j gibby/
Darin J. Gibby
Reg. No. 38,464

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, CA 94111-3834
Tel: 303-571-4000
Fax: 415-576-0300
DJG/cl
61034945 v1